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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,598	04/27/2007	John E. O'Gara	59894US(49991)	3666
48990	7590	03/22/2010	EXAMINER	
EDWARDS ANGELL PALMER & DODGE LLP			LOEWE, ROBERT S	
P.O. BOX 55874				
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			1796	
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			03/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,598	O'GARA, JOHN E.	
	Examiner	Art Unit	
	ROBERT LOEWE	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 April 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16, 19-34, 36, 52 and 53 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-16, 19-34, 36, 52 and 53 is/are rejected.
 7) Claim(s) 4 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/31/06, 9/2/08</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Objections

Claim 4 is objected to for the following informality: "he" should be corrected to --The--.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16, 19-34, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Gara (US Pat. 6,528,167) in view of Holloway (US Pat. 6,210,570).

Claims 1 and 52: O'Gara teaches and claims hybrid particles for chromatographic separations, wherein said particles have an interior and exterior surface, wherein the particles have the same claimed composition (claim 1). O'Gara does not teach that the hybrid particles may be converted to porous monoliths. However, Holloway teaches porous silica monoliths for

chromatographic separations (abstract). O'Gara and Holloway are combinable because they are from the same field of endeavor, namely, preparation of stationary phases for column chromatography. At the time of the invention, a person having ordinary skill in the art would have found it obvious to convert the hybrid particles as taught by O'Gara into the claimed porous monoliths and would have been motivated to do so since Holloway teaches that stationary phases which are comprised of a packed column of particles can cause reduction of flow rates which necessitates higher column pressure (1:49-56). Holloway teaches that stationary phases comprising a continuous network (i.e., monolithic stationary phases) are alternatives which do not suffer from such drawbacks (1:57-59). A person having ordinary skill in the art understands from the teachings of Holloway that monolith formation is the result of gelation of the hydrosols taught therein. It is submitted that the amount of experimentation needed to prepare silica monoliths from the materials taught by O'Gara would not be undue given the disclosure of Holloway. Further, a person having ordinary skill in the art understands that when carrying out sol-gel reactions, advanced aging leads to the formation of networks of silica-based materials instead of discrete particles.

Instant claim 52 is a product-by-process claim. For such claims, patentability is based on the product itself, and not on its method of production. Therefore, it is submitted that Holloway provides motivation to prepare silica monoliths using the compositions as taught by O'Gara. A person having ordinary skill in the art would be cognizant of maintaining/preserving the attractive physical property limitations as taught by O'Gara, namely, the specific pore volumes, average pore diameters, specific surface areas and surface concentration of the R⁶ groups. Therefore, a person having ordinary skill in the art would have found it obvious to prepare silica-

based monoliths having the claimed physical properties as taught by O'Gara. As such, there would not be expected to be substantial differences in structure of the claimed silica monoliths as compared to the silica monoliths which is suggested by the combination of O'Gara in view of Holloway.

Since many of the remaining dependent claims of O'Gara are identical to those as claimed, a summary showing which claims read on the claims of O'Gara is shown below.

Claims 2-6 of O'Gara are identical or substantially identical to instant claims 2-6, respectively.

Claims 7-9: Claims 16-18 of O'Gara are identical to instant claims 7-9.

Claims 10-16: Claims 9-12 of O'Gara are identical or substantially identical to instant claims 9-15.

Claims 19-22: Claims 19-22 of O'Gara are identical or substantially identical to instant claims 19-22.

Claims 23-33: Claims 25-35 of O'Gara are identical or substantially identical to instant claims 23-29.

Claim 34: O'Gara teaches that the inorganic/organic hybrid particles have chromatographically-enhancing pore geometry (17:18-20).

Claim 53: O'Gara prepares hybrid particles having surface silicon-alkyl groups (example 1). O'Gara further teaches replacing one or more surface silicon-alkyl groups with fluoride, then with hydroxyl groups (Scheme on columns 15 and 16 and Example 6). O'Gara further teaches further modification of the surface methyl group converted hybrid inorganic/organic particles with a substituted siloxane group followed by end-capping with a trialkylhalosilane (example 9).

O'Gara does not teach that the hybrid particles may be converted to porous monoliths. However, Holloway teaches porous silica monoliths for chromatographic separations (abstract). O'Gara and Holloway are combinable because they are from the same field of endeavor, namely, preparation of stationary phases for column chromatography. At the time of the invention, a person having ordinary skill in the art would have found it obvious to convert the hybrid particles as taught by O'Gara into the claimed porous monoliths and would have been motivated to do so since Holloway teaches that stationary phases which are comprised of a packed column of particles can cause reduction of flow rates which necessitates higher column pressures (1:49-56). Holloway teaches that stationary phases comprising a continuous network (i.e., monolithic stationary phases) are alternatives which do not suffer from such drawbacks (1:57-59). A person having ordinary skill in the art understands from the teachings of Holloway that monolith formation is the result of gelation of the hydrosols taught therein. It is submitted that the amount of experimentation needed to prepare silica monoliths from the materials taught by O'Gara would not be undue given the disclosure of Holloway. Further, a person having ordinary skill in the art understands that when carrying out sol-gel reactions, advanced aging leads to the formation of networks of silica-based materials instead of discrete particles.

Claims 1-16, 19-34, 36, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walter et al. (US 2003/0150811) in view of O'Gara (US Pat. 6,528,167).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 1-16, 19-34 and 52: Walter et al. teaches porous inorganic/organic hybrid monolith materials for chromatographic separations and processes for their preparation. The hybrid monoliths possess all of the structural features of the instant claims (pore diameters (paragraph 0133), specific surface areas and pore volumes (paragraph 0151)). The difference between Walter et al. and the instant claims is the presence of B units, which are derived from surface treatment of silicon-bonded alkyl groups. However, based on the teachings of O'Gara, a person having ordinary skill in the art would have been motivated to carry out such a surface treatment step in the manner as taught by O'Gara and would have been motivated to do so since O'Gara teaches that replacement of the surface silicon-methyl groups with silanol groups result in hybrid particles with improved pH stability and improved chromatographic separation performance including peak tailing (2:20-24). Walter and O'Gara are combinable because they

are from the same field of endeavor, namely, the preparation of silica based materials for chromatographic separations.

O'Gara explicitly teaches the same surface groups as required by the instant claims including situations wherein the surface R⁴ groups may be hydroxyl, fluorine, methoxy and of the formula -OSi(R⁵)₂-R⁶, a C₁₈ group and a cyanopropyl group. Further O'Gara explicitly teaches the same claimed surface concentration of the R⁶ groups according to instant claims 19-22.

Claim 36: Walter et al. teaches porous inorganic/organic hybrid monolith materials for chromatographic separations and processes for their preparation. The specific process as taught by Walter et al. is identical in all aspects to that as claimed with the exception of step (g) (paragraphs 0089-0098). However, based on the teachings of O'Gara, a person having ordinary skill in the art would have been motivated to carry out such a surface treatment step [step (g) as claimed] in the manner as taught by O'Gara and would have been motivated to do so since O'Gara teaches that replacement of the surface silicon-methyl groups with silanol groups result in hybrid particles with improved pH stability and improved chromatographic separation performance including peak tailing (2:20-24). Walter and O'Gara are combinable because they are from the same field of endeavor, namely, the preparation of silica based materials for chromatographic separations. Further, O'Gara also further functionalizes the hybrid silica particles taught therein (example 9 of O'Gara), such a step corresponding to step (j) of paragraph 0099.

Claim 53: Walter et al. teaches porous inorganic/organic hybrid monolith materials for chromatographic separations and processes for their preparation. Walter et al. explicitly teaches

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steps (a), (d) and (e) of instant claim 53. While steps (b) and (c) are not taught by Walter et al., the inclusion of such a step is believed to be obvious to a person having ordinary skill in the art in view of O'Gara. Walter and O'Gara are combinable because they are from the same field of endeavor, namely, the preparation of silica based materials for chromatographic separations. O'Gara teaches that replacement of the surface silicon-methyl groups with silanol groups result in hybrid particles with improved pH stability and improved chromatographic separation performance including peak tailing (2:20-24). The preparation of such materials proceeds via the conversion of silicon-bonded alkyl groups to silicon-bonded fluoride groups, followed by conversion to silicon-bonded hydroxyl groups (scheme on columns 15 and 16 of O'Gara).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 13-17 and 50-55 of copending Application No. 11/631,341. Although the conflicting claims are not identical, they are not patentably distinct from each other because formula (III) of claim 2 of the '341 Application is the same as formula I of instant claim 1 and reads on instant claims 1-3. The recited dependent claims of the '341 Application read on instant claims 4-15.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,250,214 in view of O'Gara (US Pat. 6,528,167).

Claim 1 of the '214 patent is substantially similar in scope for formulae II and III of instant claims 1 and 52. The key difference between the two claims is that the instant claims further have units of formula (IV), which are derived from the surface replacement of silicon-bonded alkyl groups with the silicon-bonded groups, R⁴ as claimed. However, such a treatment step of the monoliths of claim 1 of the '214 patent is believed to be obvious given the teachings of O'Gara. Specifically, O'Gara teaches that replacement of the surface silicon-methyl groups with silanol groups result in hybrid particles with improved pH stability and improved chromatographic separation performance including peak tailing (2:20-24). With this knowledge, a person having ordinary skill in the art would have found it obvious to perform the same surface modifications of the hybrid silica particles as taught by O'Gara to the porous hybrid monolith

materials as claimed in the '214 patent; the result being the instantly claimed porous inorganic/organic hybrid monolith material.

Relevant Art Cited

Additional prior art documents which are relevant to Applicants invention can be found on the attached PTO-892 form.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Loewe whose telephone number is (571) 270-3298. The examiner can normally be reached on Monday through Friday from 5:30 AM to 3:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Robert Loewe/
Patent Examiner, Art Unit 1796
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